

**IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA,

No. 4:17-CR-00403

v.

(Chief Judge Brann)

RAYMOND KRAYNAK,

Defendant.

MEMORANDUM OPINION

SEPTEMBER 3, 2021

I. BACKGROUND

In 2017, Raymond Kraynak—a doctor of osteopathy who was registered by the Drug Enforcement Administration to prescribe Schedule II, III, IV, and V controlled substances—was indicted on twelve counts of unlawfully distributing and dispensing a controlled substance, in violation of 21 U.S.C. § 841(a)(1), five counts of unlawfully distributing and dispensing a controlled substance resulting in death, in violation of 21 U.S.C. § 841(a)(1), and two counts of maintaining a drug-involved premises, in violation of 21 U.S.C. § 856(a)(1).¹

In Count Thirteen of the indictment, Dr. Kraynak is charged with causing the death of R.C. by prescribing Alprazolam, Hydrocodone, Carisoprodol; in Count Fourteen with causing the death of D.H. by prescribing Oxycodone; in Count Fifteen with causing the death of A.K. by prescribing Oxycodone and Alprazolam; in Count

¹ Doc. 3.

Sixteen with causing the death of M.L. by prescribing Temazepam, Alprazolam, and Hydrocodone; and in Count Seventeen with causing the death of C.S. by prescribing Oxycodone, Carisoprodol, Diazepam, and Zolpidem.²

In early 2020, both Kraynak and the Government exchanged notices of expert testimony, with the Government asserting that it intended to offer testimony from Stephen M. Thomas, M.D., and Kraynak asserting that he intended to offer testimony from Carol Warfield, M.D.³ In March 2020, Kraynak filed a motion to exclude the expert testimony of Dr. Thomas.⁴ On August 5, 2020, this Court conducted a *Daubert* hearing on that motion and, on November 9, 2020, the Court denied that motion.⁵

On February 4, 2021, the Court set this matter for trial to commence September 7, 2021 and imposed a series of pretrial deadlines, including that pretrial motions be filed by May 10, 2021, and motions *in limine* be filed by June 7, 2021.⁶ By June 7, 2021, Kraynak had not provided the Government with a summary of Dr. Warfield's testimony and, accordingly, the Government filed a motion to compel Kraynak to produce that summary.⁷

² *Id.* at 19.

³ Doc. 53.

⁴ Doc. 57.

⁵ Docs. 90, 93, 94.

⁶ Doc. 101.

⁷ Doc. 127.

Despite the deadlines set forth above, at a pretrial conference held on August 9, 2021, one month prior to trial, counsel for the Defendant informed the Court and the Government that he was attempting to hire an expert toxicologist. On August 13, 2021, Kraynak provided the Government with a very brief notice of expert opinion related to the proposed testimony of Susan M. Skolly-Danziger, Pharm.D.⁸ This belatedly disclosed notice of expert testimony provoked a corresponding motion to exclude, which the Government filed on August 18, 2021.⁹ Kraynak has since submitted a more thorough summary of Dr. Skolly-Danziger's proposed testimony.¹⁰

A. Dr. Skolly-Danziger's Proposed Expert Testimony

Dr. Skolly-Danziger offers opinions regarding the five decedents whose deaths form the basis of Counts Thirteen through Seventeen.

1. Opinion Regarding R.C.

As to R.C., the victim identified in Count Thirteen of the Indictment, Dr. Skolly-Danziger noted that some of R.C.'s prescription history is incomplete because hydrocodone was not reported in Pennsylvania's centralized database until 2016—after the events at issue in this Count of the Indictment—and, thus, there is

⁸ Doc. 165-1.

⁹ Doc. 164.

¹⁰ Doc. 170.

little information about R.C.'s hydrocodone prescription history.¹¹ Postmortem blood tests revealed the presence of 38 mcg/mL of Acetaminophen, 550 ng/mL of hydrocodone, and 4.4 ng/mL of hydromorphone.

Dr. Skolly-Danziger noted that R.C.'s test was reportedly drawn from the femoral region,¹² which is important because femoral blood is furthest from the organs in the center of the body and, thus, is less likely to be contaminated by the high levels of drugs that are present in those organs.¹³ Nevertheless, Dr. Skolly-Danziger questioned "whether the sample was femoral blood as the volume was 35 mL since the femoral vein does not hold typically more than 20 mL of blood."¹⁴ Moreover, she found it notable that the blood sample was not treated with an anticoagulant or anti-enzymatic agent, because blood may clot or suffer from "biotransformation of some particular drugs" without such anticoagulant or anti-enzymatic agents.¹⁵ Because R.C.'s blood was not treated with an anticoagulant, the blood did clot; in Dr. Skolly-Danziger's opinion, it is possible that, in the process of rehydrating the blood, too much or too little fluid was introduced, which may have impacted drug concentrations within the blood sample.¹⁶

¹¹ Doc. 174 at 11-12. Although not relevant to the disposition of this motion, it is notable that the absence of records related to R.C.'s hydrocodone prescription history is traceable to the fact that Kraynak's records were, as Dr. Thomas opined, substandard and incomplete.

¹² Doc. 170 at 5.

¹³ Doc. 174 at 13-14.

¹⁴ Doc. 170 at 6.

¹⁵ Doc. 174 at 14-15.

¹⁶ *Id.* at 15-16.

Dr. Skolly-Danziger opined that hydrocodone has been found lethal with blood levels ranging from 120 to 1600 ng/ML, which vary by person based upon a number of factors, including drug tolerance.¹⁷ Nevertheless, the levels of hydrocodone present in R.C.'s system were "far beyond any blood level that would be possible for a patient to achieve who followed a regimen of taking hydrocodone/acetaminophen 10/325 mg three times a day," which was the substance and amount that R.C. was prescribed.¹⁸

Dr. Skolly-Danziger further opined that "[b]ecause both hydrocodone and acetaminophen are combined in one tablet, I would expect that the level of acetaminophen would have been much higher if the Decedent took more medication than recommended (i.e., 120 tablets to be given over 30 days at 4 times a day)."¹⁹ Dr. Skolly-Danziger hypothesized that there are two possible reasons for that discrepancy: "1) [t]he Decedent could not process or metabolize the hydrocodone due to enzymatic issues including CYP2D6 inhibition and/or 3A4 inhibition and/or 2) [t]he Decedent ingested a separate source of hydrocodone other than what is known from what was dispensed."²⁰

Dr. Skolly-Danziger posited that the first explanation is "likely" the correct explanation.²¹ She reaches that conclusion because of the presence of

¹⁷ *Id.* at 8.

¹⁸ *Id.* at 10.

¹⁹ *Id.*

²⁰ *Id.* at 10-11.

²¹ *Id.* at 11.

diphenhydramine, which “inhibit[s] the metabolism of the Hydrocodone and therefore [may] lead to the higher levels of the Hydrocodone in the blood.”²²

2. Opinion Regarding D.H.

With respect to D.H., the victim identified in Count Fourteen of the Indictment, Dr. Skolly-Danziger observed that blood tests after D.H.’s death revealed the presence of numerous drugs, “including barbiturates, cannabinoids, salicylates (aspirin), amphetamines, antidepressants, antihistamines, antipsychotic agents, benzodiazepines, CNS stimulants, cocaine and metabolites, hallucinogens, sedatives/hypnotics, hypoglycemics, muscle relaxants, non-steroidal anti-inflammatory agents, opiates, opioids, and other analytes.”²³ Blood tests also revealed 796 ng/mL of oxycodone and 17.6 ng/mL of oxymorphone.²⁴ No autopsy was performed²⁵ which, according to Dr. Skolly-Danziger, means that possible causes of death other than drugs cannot be eliminated.²⁶

D.H.’s blood sample was drawn from the heart, and Dr. Skolly-Danziger opined that heart blood should only be used as a last resort, since the heart “can be close to gastric contents and may pick up some unabsorbed gastric contents, particularly . . . remnants of pills that were not absorbed in the blood.”²⁷ Moreover,

²² Doc. 174 at 21-22.

²³ Doc. 170 at 11.

²⁴ *Id.* at 12.

²⁵ *Id.*

²⁶ Doc. 174 at 23-24.

²⁷ *Id.* at 24.

“heart blood . . . may be contaminated from other areas, destruction from other areas that are rich sources of drug contents such as lungs, liver, also the heart.”²⁸ The reliability of D.H.’s blood sample may further be compromised, in Dr. Skolly-Danziger’s opinion, by D.H.’s prior gastric bypass surgery, which Dr. Skolly-Danziger stated may result in a longer absorption time for drugs, which in turn means that there is a higher drug concentration in the gastric contents that could be absorbed into the heart blood.²⁹ In Dr. Skolly-Danziger’s view, “[t]he only way to determine this was not the case was to obtain a peripheral blood specimen such as femoral blood and compare the drug concentration to that of the central blood (heart blood).”³⁰ Dr. Skolly-Danziger speculated that “[t]he Decedent’s specimen . . . [was] likely contaminated by gastric contents.”³¹

Dr. Skolly-Danziger further asserted that no anticoagulants or preservatives were used in the blood sample, which may impact the sample.³² Dr. Skolly-Danziger also noted that “[p]ostmortem drug concentrations in blood may not always reflect ante-mortem drug concentrations in blood due to the movement of drugs after death. The phenomenon is referred to as post-mortem redistribution (PMR) . . . When PMR

²⁸ *Id.*

²⁹ *Id.* at 23. Because drugs are often not absorbed well by individuals who have had gastric bypass surgery, Dr. Skolly-Danziger opines that “long-acting drugs . . . really should not be used in someone who has a gastric bypass.” *Id.* at 29. This testimony directly undermines any notion that Kraynak issued opioid prescriptions to D.H. within the usual course of professional practice and for a legitimate medical purpose.

³⁰ Doc. 170 at 15.

³¹ *Id.* at 14.

³² *Id.* at 12-13.

occurs, blood specimens drawn from the central body cavity and heart generally will have higher drug concentrations post-mortem than specimens drawn from peripheral areas, most commonly the femoral vein.”³³ She concluded that the “postmortem oxycodone concentration of 796 ng/mL was exceptionally high. The Decedent’s oxycodone concentration was approximately 8 times higher than concentrations of oxycodone attained by following recommendations in the package insert.”³⁴

3. Opinion Regarding A.K.

With regard to A.K., the victim identified in Count Fifteen of the Indictment, Dr. Skolly-Danziger opined that A.K.’s issues with blood sugar may have slowed the absorption of drugs.³⁵

Post-mortem blood tests revealed the presence of alprazolam at 290 ng/mL, which Dr. Skolly-Danziger opined is “extremely high,” well above therapeutic levels,³⁶ and is “consistent with intentional overuse or abuse.”³⁷ Despite the extremely high levels of alprazolam, Dr. Skolly-Danziger observed that, as a general matter, an overdose of alprazolam “lead[s] to sedation but not to death” unless it is combined with other drugs because alprazolam does not bind well to the respiratory center of the brain.³⁸ In contrast, Dr. Skolly-Danziger opined that, in contrast, the

³³ *Id.* at 15.

³⁴ *Id.* at 14.

³⁵ Doc. 174 at 30.

³⁶ *Id.* at 31.

³⁷ Doc. 170 at 19.

³⁸ *Id.* at 33-35.

level of oxycodone in A.K. was at or near therapeutic levels³⁹ and, given the low levels of other drugs, it is “not a slam dunk” that alprazolam combined with other drugs killed A.K.⁴⁰

4. Opinion Regarding M.L.

As to M.L., the victim identified in Count Sixteen of the Indictment, Dr. Skolly-Danziger noted the blood sample was again drawn from the heart and was not preserved with any anticoagulants or preservatives.⁴¹ Tests of that sample revealed several drugs in M.L.’s system, including, among others, temazepam at 393 ng/mL, alprazolam at 218 ng/mL, and hydrocodone at 183 ng/mL.⁴²

Dr. Skolly-Danziger opined that the levels of alprazolam and hydrocodone exceeds the levels that would be present had M.L. used the substances as prescribed, and that the absence of analgesics (such as acetaminophen) in M.L.’s blood is “suspicious if the Decedent had ingested the product Vicodin, which is hydrocodone combined with acetaminophen.”⁴³ In Dr. Skolly-Danziger’s opinion, this absence indicates “that either, the Decedent used a form of hydrocodone that did not contain acetaminophen, the blood specimen is not that of the Decedent, or the blood was not tested for acetaminophen.”⁴⁴ Furthermore, Dr. Skolly-Danziger opined that the level

³⁹ *Id.* at 37.

⁴⁰ *Id.* at 65.

⁴¹ *Id.* at 38-39.

⁴² Doc. 170 at 20.

⁴³ *Id.* at 21.

⁴⁴ *Id.*

of pregabalin is above the level that has been associated with toxic effects.⁴⁵

5. Opinion Regarding C.S.

As to C.S., the victim identified in Count Seventeen of the Indictment, Dr. Skolly-Danziger noted that

a prescription for 150 tablets of oxycodone 30 mg was . . . written by Dr. Kraynak and filled by [an] independent pharmacy on April 22, 2014. The directions for the oxycodone were to take one (1) tablet every three to four hours if needed [for pain]. A review of C.S.'s Rite-Aid prescription history from December 11, 2012, to October 16, 2015, shows the Decedent had filled 150 tablets of 30mg of oxycodone on April 29, 2014. The prescription for the 150 tablets of oxycodone was written and filled just 7 days after the last oxycodone prescription was written and filled.⁴⁶

Blood tests revealed the presence of multiple drugs in C.S.'s system, including oxycodone at 991 ng/mL and oxymorphone at 171 ng/mL; these quantities indicated to Dr. Skolly-Danziger that C.S. may have been a "rapid metabolizer," meaning that her body rapidly converted oxycodone into highly potent oxymorphone.⁴⁷ In general, individuals who are rapid metabolizers may have higher levels of oxymorphone than a doctor would otherwise predict.⁴⁸ Dr. Skolly-Danziger opined that the levels of oxycodone and oxymorphone in C.S.'s blood far exceeded the therapeutic range and was inconsistent with taking the drugs as prescribed,⁴⁹ although all other drugs in

⁴⁵ *Id.*

⁴⁶ *Id.* at 23.

⁴⁷ Doc. 174 at 43-44.

⁴⁸ *Id.* at 44.

⁴⁹ *Id.* at 45.

C.S.’s system were within therapeutic levels.⁵⁰

B. Motion to Exclude

As discussed previously, Kraynak’s patently untimely expert disclosure prompted the Government to file a motion to exclude that expert testimony.⁵¹ Based on subsequent disclosures from the defense and the *Daubert* hearing conducted in this matter on August 26, 2021, the Government has narrowed the scope of its motion and concedes that Dr. Skolly-Danziger is qualified to testify as a toxicology, pharmacology, and pharmacy expert.⁵²

The Government argues that Dr. Skolly-Danziger’s opinions should nevertheless be excluded for three reasons. First, the Government argues that her opinions are not reliable because she merely presents “selective, isolated possibilities based on unknown and hypothetical facts, suspicions, and generalized concerns as challenges to the post-mortem toxicological analysis of blood samples from deceased victims” that “rest on subjective beliefs, unknown information, and speculation, unsupported by facts specific to this case.”⁵³

Second, the Government contends that Dr. Skolly-Danziger’s opinion does not fit the case and will not assist the jury in resolving relevant disputed factual issues, as she does not offer any conclusions based on medical expertise, her

⁵⁰ Doc. 170 at 25.

⁵¹ Doc. 164.

⁵² See Doc. 174 at 6-7.

⁵³ Doc. 175 at 1. See *id.* at 1-9.

“opinion does not embrace either the application of medical judgment to Kraynak’s prescribing behavior, or an interpretation of Kraynak’s medical judgment in prescribing controlled substances,” and because her opinion focuses to some extent on the patients’ conduct, rather than Kraynak’s conduct.⁵⁴ Finally, the Government asserts that Dr. Skolly-Danziger’s opinion should be excluded because the prejudicial effect of her opinion substantially outweighs any probative value that it offers.⁵⁵

The parties have filed supplemental briefing following the conclusion of the *Daubert* hearing and, as such, this matter is now ripe for disposition.⁵⁶ For the following reasons, the Government’s motion will be granted.

II. DISCUSSION

Federal Rules of Evidence 702 and 703 govern the admissibility of expert testimony and set forth certain criteria for admissibility. Expanding upon those Rules, the United States Supreme Court set out the standard for admissibility of expert testimony in *Daubert v. Merrell Dow Pharm., Inc.*⁵⁷ The Court in *Daubert* delegated to district courts a “gatekeeping responsibility” under Rule 702, which requires that courts determine at the outset whether an expert witness may “testify to (1) scientific knowledge that (2) will assist the trier of fact.”⁵⁸ That gate-keeping

⁵⁴ *Id.* at 10; *see id.* at 9-14.

⁵⁵ *Id.* at 14-15.

⁵⁶ Docs. 175, 176.

⁵⁷ 509 U.S. 579 (1993).

⁵⁸ *Id.* at 592.

function demands an assessment of “whether the reasoning or methodology underlying the testimony is scientifically valid” as well as “whether that reasoning or methodology properly can be applied to the facts in issue.”⁵⁹ A district court “exercises more control over experts than over lay witnesses,” since “[e]xpert evidence can be both powerful and quite misleading because of the difficulty in evaluating it.”⁶⁰

Following *Daubert*, the United States Court of Appeals for the Third Circuit cast expert admissibility determinations in light of three basic requirements: (1) qualification; (2) reliability; and (3) fit.⁶¹ The qualification prong demands that the proffered expert possess sufficient “specialized knowledge” to testify as an expert.⁶² To satisfy the reliability prong, an expert’s opinion “must be based on the ‘methods and procedures of science’ rather than on ‘subjective belief or unsupported speculation.’”⁶³ The Third Circuit has set forth eight non-exclusive factors that “a district court should take into account” when deciding the reliability of expert testimony:

(1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique’s operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness

⁵⁹ *Id.* at 592-93.

⁶⁰ *Id.* at 595 (internal quotation marks omitted).

⁶¹ *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741-43 (3d Cir. 1994) (“*Paoli II*”).

⁶² *Id.* at 741.

⁶³ *Id.* at 742 (quoting *Daubert*, 509 U.S. at 589).

testifying based on the methodology; and (8) the non-judicial uses to which the method has been put.⁶⁴

With regard to the fit prong, the Third Circuit explained that admissibility “depends . . . on the proffered connection between the scientific research or test result . . . and [the] particular disputed factual issues.”⁶⁵

The burden of proof for admissibility of expert testimony falls upon the party that seeks to introduce the evidence.⁶⁶ However, as the Third Circuit has emphasized, “[t]he test of admissibility is not whether a particular scientific opinion has the best foundation or whether it is demonstrably correct. Rather, the test is whether the particular opinion is based on valid reasoning and reliable methodology.”⁶⁷

This standard is not intended to be a high one, nor is it to be applied in a manner that requires the plaintiffs to prove their case twice—they do not have to demonstrate to the judge by a preponderance of the evidence that the assessments of their experts are correct, they only have to demonstrate by a preponderance of evidence that their opinions are reliable.⁶⁸

District courts must always be cognizant of the fact that “[t]he analysis of the conclusions themselves is for the trier of fact when the expert is subjected to cross-examination.”⁶⁹

⁶⁴ *Id.* at 742 n.8.

⁶⁵ *Id.* at 743 (internal quotation marks omitted).

⁶⁶ *Oddi v. Ford Motor Co.*, 234 F.3d 136, 145 (3d Cir. 2000)

⁶⁷ *Id.* (internal quotation marks omitted).

⁶⁸ *Id.* (internal quotation marks omitted).

⁶⁹ *Id.* (internal quotation marks omitted).

A. Timeliness of the Proposed Expert Opinion

First, although not raised by the Government, the Court notes that notice of Kraynak’s proposed expert witness was untimely, with Kraynak having provided notice of the witness to the Government on August 13, 2021—less than one month prior to the commencement of trial on September 7, 2021.⁷⁰

Federal Rule of Criminal Procedure 16(b)(1)(C) provides that, at the Government’s request, a defendant must

give to the government a written summary of any testimony that the defendant intends to use under Rules 702, 703, or 705 of the Federal Rules of Evidence as evidence at trial, if—(i) the defendant requests disclosure under subdivision (a)(1)(G) [providing for government disclosure of its expert witnesses] and the government complies . . . This summary must describe the witness’s opinions, the bases and reasons for those opinions, and the witness’s qualifications.

That Rule is “intended to minimize surprise that often results from unexpected expert testimony, reduce the need for continuances, and to provide the opponent with a fair opportunity to test the merit of the expert’s testimony through focused cross-examination.”⁷¹ “Significantly, although no specific timing requirements are included, it is expected that the parties will make their requests and disclosures in a timely fashion.”⁷² Exclusion of expert witnesses is warranted “when defendants fail to serve timely notice of their intent to call them as witnesses.”⁷³

⁷⁰ Doc. 165-1 at 1.

⁷¹ *United States v. Hoffecker*, 530 F.3d 137, 185 (3d Cir. 2008) (internal quotation marks omitted).

⁷² *Id.* (brackets and internal quotation marks omitted).

⁷³ *Id.*

In January 2020 Kraynak requested notice of expert testimony, which the Government provided.⁷⁴ This triggered a reciprocal obligation for Kraynak to provide the Government with a summary of its proposed expert witnesses,⁷⁵ and to do so in a timely manner.⁷⁶ It is simply not possible to conclude that Kraynak's disclosure—less than one month prior to a trial that is itself expected to last approximately one month—may be deemed timely, particularly when more than 43 months has passed between the date of the indictment and the date that Kraynak provided notice of the proposed expert testimony.⁷⁷

Nevertheless, despite the incredible delay in submitting the notice of proposed expert testimony to the Government, the Court recognizes that the Government still had approximately twenty-five days to prepare to counter that expert testimony at trial, which appears to be a sufficient amount of time for the Government to prepare for trial and was sufficient time for the Government to file this motion to exclude. Accordingly, although the Court is displeased with the production of a new proposed expert witness so close to trial, it will not exclude that witness pursuant to Rule 16.

B. Reliability of the Proposed Expert Opinion

Turning then to the reliability of Dr. Skolly-Danziger's opinions, the Court concludes that her opinions are largely unreliable, as many of her conclusions are

⁷⁴ Doc. 52.

⁷⁵ Fed. R. Crim. P. 16(b)(1)(C).

⁷⁶ *Hoffecker*, 530 F.3d at 185.

⁷⁷ *See id.* at 188 (finding it significant that the defendant “had 34 months after his indictment to obtain the” excluded expert testimony).

based upon speculation.

1. Opinion as to R.C.

With regard to blood tests conducted on R.C., Dr. Skolly-Danziger testified at the *Daubert* hearing that the blood sample that was drawn was not treated with an anticoagulant or anti-enzymatic agent and, as a result, the blood clotted.⁷⁸ She noted that, as a result of that clot, fluid needed to be added to the blood, and there was no indication of how much fluid was added.⁷⁹ Dr. Skolly-Danziger noted that, if too much fluid is added, the tests results will be diluted but, if too little fluid is added, the results will be inflated.⁸⁰ However, she was unable to offer an opinion as to what happened with R.C.’s test and testified at the *Daubert* hearing that “it’s unknown how did it affect the concentration of any substances that were in this collected blood, especially after this clotting event. And so this—this is unknown, and it can affect, then, the analyzed blood as to the concentration.”⁸¹

Dr. Skolly-Danziger’s opinion as to how clotting may have impacted the sample of R.C.’s blood relies far too heavily on speculation to be deemed reliable since, by her own admission, it is entirely “unknown” how or if the clotting and rehydration of that blood impacted the blood sample. There similarly is no evidence that the absence of preservatives had any impact on the blood sample.

⁷⁸ Doc. 174 at 14-16.

⁷⁹ *Id.* at 15-17.

⁸⁰ *Id.* at 16.

⁸¹ *Id.*

Dr. Skolly-Danziger next opined that “[b]ecause both hydrocodone and acetaminophen are combined in one tablet, I would expect that the level of acetaminophen would have been much higher if the Decedent took more medication than recommended (i.e., 120 tablets to be given over 30 days at 4 times a day).”⁸² Dr. Skolly-Danziger hypothesized that it is “likely” that “[t]he Decedent could not process or metabolize the hydrocodone due to enzymatic issues including CYP2D6 inhibition and/or 3A4 inhibition.”⁸³ Dr. Skolly-Danziger explained at the *Daubert* hearing that the presence of diphenhydramine (Benadryl) “inhibit[s] the metabolism of the Hydrocodone and therefore [may] lead to the higher levels of the Hydrocodone in the blood.”⁸⁴ Dr. Skolly-Danziger was unable to express that opinion with any definitiveness, and explained that it was merely “a suspicion of” hers that her explanation was correct, despite the fact that the diphenhydramine in R.C.’s system was not “all that high.”⁸⁵

Dr. Skolly-Danziger’s opinion is again based solely on supposition and speculation. She cannot conclude with any reasonable certainty either that the presence of Benadryl in R.C.’s system led to the elevated levels of hydrocodone in comparison to the levels of acetaminophen, or why the levels of hydrocodone and acetaminophen are not in proportion. Moreover, her conclusions here are directly at

⁸² *Id.*

⁸³ *Id.* at 10-11.

⁸⁴ Doc. 174 at 21-22.

⁸⁵ *Id.* at 21.

odds with her earlier speculative opinion that the blood sample was untrustworthy and may have been compromised by the lack of preservatives or the amount of fluid used to rehydrate the blood; if the sample were compromised, then Dr. Skolly-Danziger would necessarily be unable to testify as to what the test results mean.

2. Opinion as to D.H.

With respect to D.H., the blood sample was drawn from the heart, and Dr. Skolly-Danziger opined that heart blood is “close to gastric contents and may pick up some unabsorbed gastric contents, particularly . . . remnants of pills that were not absorbed in the blood” and “may be contaminated from other areas, destruction from other areas that are rich sources of drug contents such as lungs, liver, also the heart.”⁸⁶ This is particularly so, Dr. Skolly-Danziger opined, because D.H. had prior gastric bypass surgery, which may result in a longer absorption time for drugs, which in turn means that the gastric contents absorbed into the heart blood may have a higher drug concentration.⁸⁷ Dr. Skolly-Danziger then opined that the blood test was “likely contaminated by gastric contents.”⁸⁸

The conclusion that D.H.’s blood test was likely contaminated by gastric contents or the contents of other organs is again highly speculative. While it may be accurate that, as a general matter, gastric bypass surgery results in increased levels of drugs in gastric contents, and that gastric contents may sometimes contaminate

⁸⁶ Doc. 170 at 24.

⁸⁷ *Id.* at 23.

⁸⁸ *Id.* at 15.

heart blood through the process of postmortem redistribution or by other means, there is no evidence whatsoever that this occurred here.⁸⁹ Moreover, Dr. Skolly-Danziger's conclusion "within a reasonable degree of medical certainty"⁹⁰ that gastric contents contaminated the blood sample is directly undermined by her assertion that "[t]he only way to determine [that contamination did not occur is] to obtain a peripheral blood specimen such as femoral blood and compare the drug concentration to that of the central blood (heart blood),"⁹¹ which she did not, and could not, do. In light of these contradictory assertions and clear speculation, this portion of Dr. Skolly-Danziger's opinion is simply not reliable.

Similarly, while Dr. Skolly-Danziger again asserts that no anticoagulants or preservatives were used in the blood samples, which may impact the D.H.'s blood sample,⁹² there is no evidence that the absence of anticoagulants or preservatives had any impact on D.H.'s blood sample; indeed, unlike R.C., there is no contention that D.H.'s blood sample clotted. In the absence of any evidence related to the impact that the absence of anticoagulants or preservatives had on D.H.'s blood sample, Dr. Skolly-Danziger is unable to offer anything other than speculation as to whether and how D.H.'s blood sample may have been affected. Thus, her opinion in this respect

⁸⁹ See *id.* (noting that, when postmortem redistribution *does* occur, "blood specimens drawn from the central body cavity and heart *generally* will have higher drug concentrations post-mortem than specimens drawn from peripheral areas" (emphasis added)).

⁹⁰ Doc. 174 at 45.

⁹¹ Doc. 170 at 15.

⁹² *Id.* at 12-13.

is unreliable.⁹³

3. Opinion as to A.K.

With respect to A.K., Dr. Skolly-Danziger opined that the level of alprazolam in A.K.'s blood was "extremely high" and well above therapeutic levels,⁹⁴ but was generally unlikely to alone cause death because alprazolam does not bind well to the respiratory center of the brain and generally must be combined with other drugs to be lethal.⁹⁵ She further opined that the level of oxycodone in A.K.'s blood was at or near therapeutic levels.⁹⁶ Thus, at the *Daubert* hearing Dr. Skolly-Danziger opined that, despite warnings issued by the Food and Drug Administration (FDA) that oxycodone and alprazolam should not be mixed due to the possibility of lethal consequences,⁹⁷ it was "not a slam dunk that [oxycodone], even when combined with Alprazolam, was the cause of death."⁹⁸ She testified that this should simply "be investigated" as a potential cause of death.⁹⁹

This opinion is not only highly speculative, but also falls outside of Dr. Skolly-Danziger's proffered area of expertise. During the *Daubert* hearing, Dr.

⁹³ Similarly, while Dr. Skolly-Danziger opines that no autopsy was performed, which means that no other causes of death may be excluded, Doc. 174 at 23-24, there is no evidence of any other potential means of death. Moreover, given the massive quantities of oxycodone in D.H.'s system, Doc. 62 at 8; Doc. 170 at 12, it is extremely difficult to argue that anything other than oxycodone caused D.H.'s death.

⁹⁴ Doc. 174 at 31.

⁹⁵ *Id.* at 33-35.

⁹⁶ *Id.* at 37.

⁹⁷ *Id.* at 35-36.

⁹⁸ *Id.* at 65-66

⁹⁹ *Id.*

Skolly-Danziger emphasized that she was “not trying to interpret cause and manner of death. That’s not my role here.”¹⁰⁰ Based upon these clear limitations in Dr. Skolly-Danziger’s opinion, her supposition regarding the potential cause of death for A.K. is unreliable.

Although Kraynak argues that A.K. was diabetic and could have died from sugar issues or kidney issues,¹⁰¹ there is no testimony or evidence that A.K. may have died as a result of any specific issues other than drug use. Moreover, there is no definitive evidence or testimony that A.K. was even diabetic; Dr. Skolly-Danziger was only able to offer that A.K. was taking medication that is prescribed to diabetic individuals and that “normally” people with metabolic issues with respect to blood sugar are diabetic.¹⁰² Any opinion that A.K. was diabetic, and that diabetes may have played a role in his death, is therefore entirely speculative.

Kraynak further argues that the jury must hear Dr. Skolly-Danziger’s testimony that the FDA did not issue a warning not to mix oxycodone and alprazolam until after A.K.’s death,¹⁰³ which Kraynak argues undermines Dr. Thomas’ expert opinion that Kraynak should not have prescribed this combination to A.K.¹⁰⁴ However, any testimony from Dr. Skolly-Danziger as to the propriety of

¹⁰⁰ *Id.* at 65.

¹⁰¹ Doc. 176 at 5-6.

¹⁰² Doc. 174 at 30; *see* Doc. 60 at 8-9 (Dr. Thomas describing A.K.’s medical history with no mention of diabetes).

¹⁰³ *Id.* at 35-36.

¹⁰⁴ Doc. 176 at 7.

Kraynak issuing such a prescription is inherently unreliable, as she is not a medical doctor, and would be unable to offer an opinion as to the medical judgment that is implicated when a physician issued such prescriptions prior to the FDA issuing a warning against this practice. There is no evidence that Dr. Skolly-Danziger is aware of what knowledge doctors possessed about the dangers of prescribing oxycodone and alprazolam together prior to the FDA's warning, and she is unable to offer any judgment regarding whether the prescriptions that Kraynak issued to A.K. were within the usual course of professional practice and for a legitimate medical purpose. Accordingly, any such testimony is unreliable.

4. Opinion as to M.L.

As to M.L., Dr. Skolly-Danziger noted that the blood sample was again drawn from the heart and was not preserved with any anticoagulants or preservatives.¹⁰⁵ However, Dr. Skolly-Danziger again fails to connect this hypothetical issue with any actual impact on M.L.'s blood sample. For the reasons previously discussed, her opinion on this matter cannot be deemed reliable.

Dr. Skolly-Danziger further opined that, while the levels of hydrocodone present in M.L.'s blood were above the therapeutic range, the absence of acetaminophen in M.L.'s blood is "suspicious if the Decedent had ingested the product Vicodin, which is hydrocodone combined with acetaminophen."¹⁰⁶ Dr.

¹⁰⁵ Doc. 174 at 38-39.

¹⁰⁶ Doc. 170 at 21.

Skolly-Danziger opined “that either, the Decedent used a form of hydrocodone that did not contain acetaminophen, the blood specimen is not that of the Decedent, or the blood was not tested for acetaminophen.”¹⁰⁷ This opinion offers little in the way of helpful or testable information given that, by Dr. Skolly-Danziger’s own admission, the absence of acetaminophen in M.L.’s system could be traceable to something as innocuous as the blood having not been tested for that substance. Thus, Dr. Skolly-Danziger’s opinion that the blood test results are “suspicious” amount to little more than speculation, and her opinions must be excluded as unreliable.

5. Opinion as to C.S.

With respect to C.S., Dr. Skolly-Danziger opines that, based on the fact that C.S.’s blood tests revealed the presence oxycodone at 991 ng/mL and oxymorphone at 171 ng/mL, C.S. might have been a “rapid metabolizer” who rapidly converted oxycodone into highly potent oxymorphone.¹⁰⁸ She further opines that the levels of oxycodone in C.S.’s blood far exceeded the therapeutic range and was inconsistent with taking the drugs as prescribed.¹⁰⁹ Both opinions appear to “be based on the ‘methods and procedures of science’ rather than on ‘subjective belief or unsupported speculation’”¹¹⁰ and are thus reliable. However, as discussed below, these opinions do not fit this case.

¹⁰⁷ *Id.*

¹⁰⁸ Doc. 174 at 43-44.

¹⁰⁹ *Id.* at 45.

¹¹⁰ *Paoli II* at 742 (quoting *Daubert*, 509 U.S. at 589).

C. Fit of the Proposed Expert Opinion

The Government next argues that Dr. Skolly-Danziger's opinions should be excluded because she is not able to present any opinion within a reasonable degree of medical certainty—she is not a medical doctor and cannot comment on the medical judgment involved in prescribing controlled substances or the ultimate cause of death for the five decedents.¹¹¹ Moreover, the Government asserts that Dr. Skolly-Danziger misunderstands the material issues in the case, as part of her opinion focuses on the patients' conduct after they received the prescription, rather than the doctor's conduct in issuing the prescriptions.¹¹²

Many of Dr. Skolly-Danziger's opinions that were not excluded as unreliable must nevertheless be excluded because they do not fit this case. First, Dr. Skolly-Danziger improperly focuses on the conduct of the decedents, or on matters that occurred after Kraynak issued the prescriptions. Dr. Skolly-Danziger opines that, as to all five of the decedents at issue here, the drug levels found in the decedents' blood tests are far in excess of what would result from following the recommended dosage and were consistent with abuse of the medications.¹¹³ However, this is not relevant. The Third Circuit has emphasized that the focus in cases such as this is on the conduct of the physician who prescribes a controlled substance. “[B]y placing a

¹¹¹ Doc. 175 at 9-11.

¹¹² *Id.* at 11-14.

¹¹³ Doc. 170 at 10, 14, 19, 21, 24.

prescription for a controlled substance, issued outside of the usual course of medical practice, in the hands of an ultimate user a physician completes the offense of dispensing under 21 U.S.C. § 841(a)(1),” even if the prescription is never filled.¹¹⁴

Given this context, whether one or all of the decedents abused the controlled substances or used them in excess of the recommended doses is simply irrelevant to any defense that Kraynak could proffer and, thus, provides no “connection between the scientific research or test result . . . and [the] particular disputed factual issues.”¹¹⁵ At least in the case of C.S., it could be argued that the *only* relevance of such information is to demonstrate that Kraynak did not issue the prescription in the usual course of professional practice and for a legitimate medical purpose. Kraynak issued a prescription for 150 tablets of oxycodone 30 mg to C.S., and then issued an identical prescription just seven days later.¹¹⁶ Dr. Skolly-Danziger notes that C.S. was to take one tablet every three to four hours if needed¹¹⁷ and, thus, should have used, at most, 56 tablets of oxycodone within seven days. Accordingly, each prescription, if the oxycodone were used properly, should have lasted approximately three weeks, and a request for more oxycodone after seven days is a clear indication that C.S. was abusing the medication, which should perhaps have been a warning sign to Kraynak that he should not issue a second prescription.

¹¹⁴ *United States v. Tighe*, 551 F.2d 18, 21 (3d Cir. 1977).

¹¹⁵ *Paoli II*, 35 F.3d at 743 (internal quotation marks omitted).

¹¹⁶ Doc. 170 at 23.

¹¹⁷ *Id.* at 24.

Similarly, Dr. Skolly-Danziger opined that C.S. was a rapid metabolizer who quickly turned oxycodone into the highly potent analyte oxymorphone.¹¹⁸ However, while Kraynak accurately notes this opinion, he misconstrues the relevance of this information. Although Kraynak asserts that the elevated levels of oxymorphone “indicates that the result of the blood test does not accurately reflect the postmortem controlled substance levels,”¹¹⁹ Dr. Skolly-Danziger in fact simply opines that the elevated levels only indicate that C.S. was a rapid metabolizer.¹²⁰ This opinion thus does nothing to undermine the validity of C.S.’s blood test results.

Regardless of whether C.S. was a rapid metabolizer, the blood test establishes that she had oxycodone in her blood at 991 ng/mL, which Dr. Skolly-Danziger acknowledges is far beyond the level that would be expected from therapeutic use.¹²¹ Given that C.S. indisputably had lethal quantities of oxycodone in her system, the fact that she may also have been a rapid metabolizer is irrelevant. Even if that fact were of any consequence, it has no bearing on the two relevant issues here: whether Kraynak prescribed substances in the usual course of professional practice and for a legitimate medical purpose, and whether those prescribed substances were the but-for cause of C.S.’s death. As such, this opinion also does not fit this case.

¹¹⁸ Doc. 174 at 42-43.

¹¹⁹ Doc. 176 at 10.

¹²⁰ Doc. 170 at 24.

¹²¹ *Id.* at 25.

Second, as to D.H., Dr. Skolly-Danziger opined that “[b]ecause both hydrocodone and acetaminophen are combined in one tablet, I would expect that the level of acetaminophen would have been much higher if the Decedent took more medication than recommended (i.e., 120 tablets to be given over 30 days at 4 times a day).”¹²² She theorized it is likely that the presence of diphenhydramine (Benadryl), “inhibit[ed] the metabolism of the Hydrocodone and therefore [may have] le[d] to the higher levels of the Hydrocodone in the blood.”¹²³ Regardless of whether Dr. Skolly-Danziger’s theory is correct, it is ultimately of no relevance to this case. Whether the hydrocodone levels in C.S.’s blood were increased by the presence of Benadryl has no impact on the question of whether Kraynak issued the hydrocodone prescription in the usual course of professional practice and for a legitimate medical purpose, or whether that hydrocodone actually caused C.S.’s death. Consequently, this opinion does not fit the case, and must also be excluded.

D. Admissibility Under Rule 403

Finally, the Government argues that, regardless of whether Dr. Skolly-Danziger’s opinions are admissible under *Daubert*, they should be excluded under Federal Rule of Evidence 403 because their prejudicial impact substantially outweighs any probative value.¹²⁴ The Government contends that admission of the opinion “invites speculation and conjecture and will divert the jury’s attention from

¹²² Doc. 170 at 10.

¹²³ Doc. 174 at 21-22.

¹²⁴ Doc. 175 at 14-15.

essential issues concerning the legitimate medical purpose of the prescriptions and whether the prescriptions were within the usual course of professional practice” and will likely confuse the jury.¹²⁵ The Court agrees.

The Federal Rules of Evidence provide that, to be admissible, evidence must be relevant.¹²⁶ However, pursuant to Rule 403, even relevant evidence may be excluded “if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence.”¹²⁷ “Rule 403 recognizes that a cost/benefit analysis must be employed to determine whether or not to admit evidence; relevance alone does not ensure its admissibility.”¹²⁸ “However, . . . there is a strong presumption that relevant evidence should be admitted, and thus for exclusion under Rule 403 to be justified, the probative value of evidence must be ‘substantially outweighed’ by the problems in admitting it.”¹²⁹ “This presumption in favor of admission requires weighing the maximum reasonable probative force for the offered evidence against the *likely* prejudicial impact of the evidence.”¹³⁰ “In sum, highly probative evidence is exceptionally difficult to

¹²⁵ *Id.*

¹²⁶ FED. R. EVID. 402.

¹²⁷ FED. R. EVID. 403.

¹²⁸ *GN Netcom, Inc. v. Plantronics, Inc.*, 930 F.3d 76, 85 (3d Cir. 2019) (internal quotation marks omitted).

¹²⁹ *Id.* (citations and internal quotation marks omitted).

¹³⁰ *Id.* (internal quotation marks omitted).

exclude.”¹³¹

Here, Dr. Skolly-Danziger’s opinions—to the extent that they are relevant—have limited probative value and are likely to confuse the issues and mislead the jury. As a general matter, Dr. Skolly-Danziger’s opinion with respect to the collection and preservation of blood samples appears to be well founded and unchallenged. Nevertheless, as discussed previously, Dr. Skolly-Danziger does not, and cannot, connect any shortcomings in the collection and preservation procedures of the five decedents’ blood samples with any actual errors, inconsistencies, or inaccuracies in the relevant blood samples.

Thus, not only is such testimony of limited probative value, but it would encourage the jury to speculate on the accuracy of the samples and guess as to whether the failure in some instances to use anticoagulants or preservatives had any real impact on the blood tests. The jury would be invited to delve unnecessarily into conjecture on whether and why acetaminophen was not found in certain blood tests, or whether gastric contents somehow contaminated heart blood. This would greatly distract the jury from the central questions in Counts Thirteen through Seventeen—that is, whether Kraynak issued prescriptions in the usual course of professional practice and without a legitimate medical purpose, and whether the prescribed drugs were the but-for cause of death for the five individuals identified in those Counts.

¹³¹ *Id.* (internal quotation marks omitted).

The jury would also likely be confused about the central issues in this case, and likely would be left wondering whether they need to focus on issues such as whether a decedent was a rapid metabolizer, and whether those peripheral determinations have any impact on Kraynak's guilt or innocence. Given the high likelihood that Dr. Skolly-Danziger's opinions would mislead the jury and confuse the issues, the Court concludes that any probative value of that testimony is substantially outweighed by these concerns. Consequently, Dr. Skolly-Danziger's opinions must be excluded pursuant to Rule 403.

III. CONCLUSION

For the foregoing reasons, the Court concludes that Dr. Skolly-Danziger's expert testimony is not admissible. Accordingly, the Government's motion to exclude will be granted.

An appropriate Order follows.

BY THE COURT:

s/ Matthew W. Brann

Matthew W. Brann
Chief United States District Judge